

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION

04 Civ. 9866 (RO)

**DECLARATION OF  
GREGORY A. MARKEL**

(Document filed electronically)

GREGORY A. MARKEL, being over 21 years of age, and under penalty of perjury, declares as follows:

1. I am a member of the law firm of Cadwalader, Wickersham & Taft LLP, counsel for Defendants Pfizer Inc. ("Pfizer") and Henry A. McKinnell, John L. LaMattina, Karen L. Katen, Joseph M. Feczko and Gail Cawkwell (collectively, "Defendants") in the above captioned matter. I submit this declaration in support of Defendants' Motion to Dismiss the Consolidated Class Action Complaint, dated February 16, 2006 (the "Complaint"). I make this declaration on the basis of personal information.

2. Attached hereto as Exhibit 1 are true and correct copies of excerpts of a document which has been filed under seal with the permission of this Court.

3. Attached hereto as Exhibit 1a is a true and correct copy of the American College of Physicians, Primer on Statistical Significance and P Values, which is publicly available at <http://www.acponline.org/journals/ecp/julaug01/primer.htm>.

4. Attached hereto as Exhibit 2 is a true and correct copy of the Fact Sheet that is publicly available at [http://www.cdc.gov/arthritis/data\\_statistics/ arthritis\\_related\\_statistics.htm](http://www.cdc.gov/arthritis/data_statistics/ arthritis_related_statistics.htm).

5. Attached hereto as Exhibit 3 is a true and correct copy of the Fact Sheet that is publicly available at <http://www.cdc.gov/ arthritis/arthritis/types.htm>.

6. Attached hereto as Exhibit 4 is a true and correct copy of the article by M. Michael Wolfe, M.D., David R. Lichtenstein, M.D., and Gurkirpal Singh, M.D., titled Gastrointestinal Toxicity of Nonsteroidal Anti-Inflammatory Drugs, New England Journal of Medicine, June 17, 1999.

7. Attached hereto as Exhibit 5 is a true and correct copy of the FDA Medical Officer Review of the Celebrex NDA by James Witter, M.D., Ph.D. (FDA), dated July 8, 1998, which is publicly available at [http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1\\_17\\_R-FDA-Tab-K-1.pdf](http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_17_R-FDA-Tab-K-1.pdf).

8. Attached hereto as Exhibit 6 is a true and correct copy of the Pfizer Form 8-K filed with the United States Securities and Exchange Commission (“SEC”) on January 18, 2000.

9. Attached hereto as Exhibit 7 is a true and correct copy of the Pfizer Form 8-K filed with the SEC on April 18, 2000.

10. Attached hereto as Exhibit 8 is a true and correct copy of the FDA Center for Drug Evaluation and Research, Medical Officer Review of Celebrex dated September 20, 2000 which is publicly available at [http://www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1\\_03\\_med.pdf](http://www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1_03_med.pdf).

11. Attached hereto as Exhibit 9 is a true and correct copy of the FDA Talk Paper: Labeling Changes for Arthritis Drug Celebrex dated June 7, 2002, which is publicly available at <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01151.html>.

12. Attached hereto as Exhibit 10 is a true and correct copy of the Clinical Study Synopsis of Alzheimer’s 001 Study, which is publicly available at [http://www.clinicalstudyresults.org/documents/company-study\\_76\\_0.pdf](http://www.clinicalstudyresults.org/documents/company-study_76_0.pdf).

13. Attached hereto as Exhibit 11 is a true and correct copy of New York Times article, dated February 1, 2005.

14. Attached hereto as Exhibit 12 is a true and correct copy of the Celebrex Label dated October 18, 2001, which is publicly available at [www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm).

15. Attached hereto as Exhibit 13 is a true and correct copy of the Memorandum of John K. Jenkins, M.D., Director, FDA Office of New Drugs, and Paul J. Seligman, M.D., M.P.H., Director, FDA Office of Pharmacoepidemiology and Statistical Science, Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk, dated April 6, 2005 ("FDA Decision Memorandum"), which is publicly available at <http://www.fda.gov/cder/drug/infopage /COX2/ NSAIDdecisionMemo.pdf>.

16. Attached hereto as Exhibit 14 is a true and correct copy of the FDA Bextra Approval Package, which is publicly available at [http://www.fda.gov/cder/foi/nda/2001/21-341\\_Bextra\\_Approv.pdf](http://www.fda.gov/cder/foi/nda/2001/21-341_Bextra_Approv.pdf).

17. Attached hereto as Exhibit 15 is a true and correct copy of the article by William B. White, Vibeke Strand, Richard Roberts, and Andrew Whelton titled Effects of the Cyclooxygenase-2 Specific Inhibitor Valdecoxib Versus Nonsteroidal Antinflammatory Agents and Placebo on Cardiovascular Thrombotic Events in Patients with Arthritis, 11 Amer. J. of Therapeutics 244 (July-August 2004).

18. Attached hereto as Exhibit 16 is a true and correct copy of the slides from the Joint Meeting With the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, FDA Presentation: COX-2 CV Safety: Valdecoxib-Parecoxib, by James Witter, M.D., Ph.D., dated Feb. 16, 2005 ("Witter Bextra FDA Presentation Slides"), which is publicly available at [http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4090S1\\_11\\_Witter-Valdecoxib-Parecoxib\\_files/frame.htm](http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4090S1_11_Witter-Valdecoxib-Parecoxib_files/frame.htm).

19. Attached hereto as Exhibit 17 is a true and correct copy of the FDA Notice: Joint Meeting of the Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee, dated January 19, 2005, which is available at <http://www.fda.gov/ohrms/dockets/98fr/05-958.htm>.

20. Attached hereto as Exhibit 18 is a true and correct copy of the FDA Press Release titled, "FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)" ("FDA Announcement") and dated April 7, 2005, which is publicly available at <http://www.fda.gov/bbs/topics/news/2005/NEW01171.html>.

21. Attached hereto as Exhibit 19 are a true and correct copy of the Summary Minutes for the February 16, 17 and 18, 2005 Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, dated March 6, 2005, which are available at [http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4090M1\\_Final.pdf](http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4090M1_Final.pdf).

22. Attached hereto as Exhibit 20 is a true and correct copy of a Pfizer Press Release dated April 7, 2005, which is publicly available at [http://www.pfizer.com/pfizer/are/investors\\_releases/2005pr/mn\\_2005\\_0407.jsp](http://www.pfizer.com/pfizer/are/investors_releases/2005pr/mn_2005_0407.jsp).

23. Attached hereto as Exhibit 21 are true and correct copies of certain Form 4 Statements of Changes in Beneficial Ownership of Securities for Dr. Henry A. McKinnell filed with the SEC between March 6, 1991 and August 18, 2005.

24. Attached hereto as Exhibit 22 are true and correct copies of certain Form 4 Statements of Changes in Beneficial Ownership of Securities for Dr. John L. LaMattina filed with the SEC between January 9, 2004 and May 10, 2005.

25. Attached hereto as Exhibit 23 are true and correct copies of certain Form 4 Statements of Changes in Beneficial Ownership of Securities for Karen L. Katen filed with the SEC on between March 6, 1992 and May 11, 2005.

26. Attached hereto as Exhibit 24 is a true and correct copy of the Form 3 Initial Statement of Beneficial Ownership of Securities for Dr. John L. LaMattina filed with the SEC on January 9, 2004.

27. Attached hereto as Exhibit 25 is a true and correct copy of the Pfizer Schedule 14A Proxy Statement filed with the SEC on March 16, 2006.

28. Attached hereto as Exhibit 26 is a true and correct copy of certain excerpts from the February 16, 2005 transcript of the Joint Meeting With the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, which is publicly available at <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T1.pdf>. This excerpt includes the transcripts of two FDA Presentations: (1) FDA Presentation: COX-2 CV Safety: Celecoxib, by James Witter, M.D., Ph.D. (FDA), Primary Medical Officer on the Celebrex NDA (“Witter Celebrex FDA Presentation Transcript”); and (2) FDA Presentation: COX-2 CV Safety: Valdecoxib-Parecoxib, by James Witter, M.D., Ph.D. (FDA) (“Witter Bextra FDA Presentation Transcript”).

29. Attached hereto as Exhibit 27 is a true and correct copy of the Celebrex Label dated June 7, 2002, which is publicly available at <http://www.fda.gov/cder/foi/label/2002/20998s009lbl.pdf>.

30. Attached hereto as Exhibit 28 is a true and correct copy of the Celebrex Label dated December 31, 1998, which is publicly available at <http://www.fda.gov/cder/foi/label/1998/20998lbl.pdf>.

31. Attached hereto as Exhibit 29 is a true and correct copy of the article by Elisabeth Ott et al., titled Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib [Bextra] in Patients Undergoing Coronary Artery Bypass Surgery, 125 J. Thorac. Cardiovas. Surg., no. 6, at 1481-1496 (2003).

32. Attached hereto as Exhibit 29a is a true and correct copy of the Testimony of Dr. Sidney Wolfe at the 2005 FDA Advisory Committee Meeting dated February 17, 2005, which is publicly available at <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T2.pdf>.

33. Attached hereto as Exhibit 30 are true and correct copies of the slides from the Joint Meeting With the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, FDA Presentation: COX-2 CV Safety: Celecoxib, by James Witter, M.D., Ph.D., Primary Medical Officer on the Celebrex NDA, dated Feb. 16, 2005 (“Witter Celebrex FDA Presentation Slides”), which are publicly available at [http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4090S1\\_07\\_FDA-Witter-Celebrex\\_files/frame.htm](http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4090S1_07_FDA-Witter-Celebrex_files/frame.htm).

34. Attached hereto as Exhibit 31 is a true and correct copy of the FDA Celebrex Approval Package dated December 31, 1998, which is publicly available at [http://www.fda.gov/cder/foi/nda/98/20998AP\\_appltr.pdf](http://www.fda.gov/cder/foi/nda/98/20998AP_appltr.pdf).

35. Attached hereto as Exhibit 32 is a true and correct copy of the Petition from Dr. Sidney Wolfe of the Public Citizen’s Health Research Group to the FDA to remove the Cox-2 Inhibitors Celecoxib (CELEBREX) and Valdecoxib (BEXTRA) From the Market (HRG Publication #1720) dated January 24, 2005, which is publicly available at <http://www.citizen.org/publications/release.cfm?ID=7358>.

36. Attached hereto as Exhibit 33 is a true and correct copy of the article by Fred E. Silverstein et al., titled Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis, 284 JAMA, no. 10 at 1248 (2000).

37. Attached hereto as Exhibit 34 is a true and correct copy of the Pfizer Form 10-K filed with the SEC on February 28, 2005.

38. Attached hereto as Exhibit 35 is a true and correct copy of the Pfizer Form 10-Q filed with the SEC on August 14, 2001.

39. Attached hereto as Exhibit 36 is a true and correct copy of the Pfizer Form 10-Q filed with the SEC on November 13, 2001.

40. Attached hereto as Exhibit 37 is a true and correct copy of the Pfizer Form 10-Q filed with the SEC on May 14, 2003.

41. Attached hereto as Exhibit 38 is a true and correct copy of the Pfizer Form 10-Q filed with the SEC on August 13, 2003.

42. Attached hereto as Exhibit 39 is a true and correct copy of the Pfizer Form 10-Q filed with the SEC on August 8, 2005.

43. Attached hereto as Exhibit 40 is a true and correct copy of the Pfizer Form 10-K filed with the SEC on March 10, 2004.

Dated: May 5, 2006

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/s/  
Gregory A. Markel, Esq. (GM 5626)